CLAIMS

What we claim is:

1. A process for preparing an agglutinogen preparation from a *Bordetella* strain, comprising the steps of:

(a) providing a cell paste of the *Bordetella* strain;

(b) selectively extracting fimbrial agglutinogens from the cell paste to produce a first supernatant containing said agglutinogens and a first residual precipitate;

(c) separating the first supernatant from the first residual precipitate;

(d) incubating the first supernatant at a temperature and for a time to produce a clarified supernatant containing fimbrial agglutinogens and a second precipitate containing non-fimbrial agglutinogen contaminants;

(e) concentrating the clarified supernatant to produce a crude fimbrial agglutinogen solution; and

(f) purifying fimbrial agglutinogens from the crude fimbrial agglutinogen solution to produce the fimbrial agglutinogen preparation.

2. The process of claim 1 wherein said incubation step (d) is effected at a temperature of about 75°C to about 85°C.

3. The process of claim 2 wherein the temperature is about 80°C.

4. The process of claim 2 wherein said incubation step (d) is effected for a time of about 10 minutes to about 60 minutes.

5. The process of claim 3 wherein the time is about 30 minutes.

6. The process of claim 2 wherein the fimbrial agglutinogens are selectively extracted in step (b) by dispersing the cell paste in a buffer comprising about 1M to about 6M urea.

7. The process of claim 2 wherein the first supernatant is concentrated prior to the incubation step (d).

8. The process of claim 7 wherein the concentration step (e) is effected by precipitating fimbrial agglutinogens from the clarified supernatant, separating the precipitated fimbrial agglutinogens from the resulting supernatant, and solubilizing the precipitated fimbrial agglutinogens.

9. The process of claim 8 wherein said precipitation is effected by the addition of a polyethylene glycol to the clarified supernatant.

10. The process of claim 8 wherein said precipitation is effected by adding polyethylene glycol of molecular weight about 8000 to the clarified supernatant to a concentration of about 3% to about 5 wt% to effect precipitation of said agglutinogens from the clarified supernatant.

11. The process of claim 10 wherein the concentration of polyethylene glycol is about 4.3 to about 4.7 wt%.

12. The process of claim 1 wherein the agglutinogens are purified from the crude fimbrial agglutinogen solution by column chromatography.

13. The process of claim 12 wherein said column chromatography includes Septhadex 6B and/or PEI silica column chromatography.

14. The process of claim 12 wherein said purification step includes sterilization of run through from said column chromatography purification to provide a sterile fimbrial agglutinogen preparation.

15. The process of claim 14 wherein said sterile fimbrial agglutinogen preparation is absorbed onto a mineral salt adjuvant.

16. The process of claim 15 wherein said mineral salt adjuvant is alum.

17. The process of claim 1 wherein the *Bordetella* strain is a strain of *Bordetella pertussis*.

18. A fimbrial agglutinogen preparation from a *Bordetella* strain comprising fimbrial agglutinogen 2 (Agg

2) and fimbrial agglutinogen 3 (Agg 3) substantially free from agglutinogen 1.

19. The preparation of claim 18 wherein the weight ratio of fimbrial Agg 2 to fimbrial Agg 3 is from about 1.5:1 to about 2:1.

20. The fimbrial agglutinogen preparation of claim 19 produced by a method of claim 1.

21. An immunogenic composition comprising the agglutinogen preparation of claim 18, 19 or 20.

22. The immunogenic composition of claim 21 formulated as a vaccine for *in vivo* use for protecting a host immunized therewith from disease caused by *Bordetella*.

23. The immunogenic composition of claim 22 further comprising at least one other *Bordetella* antigen.

24. The immunogenic composition of claim 23 wherein the at least one other *Bordetella* antigen is selected from the group consisting of filamentous haemagglutinin, the 69 kDa outer membrane protein, adenylate cyclase, *Bordetella* lipooligosaccharide, outer membrane proteins and pertussis toxin or a toxoid thereof.

25. The immunogenic composition of claim 24 comprising pertussis toxoid, filamentous haemagglutinin and fimbrial agglutinogens of *B. pertussis* in a weight ratio of about 2:1:1.

26. The immunogenic composition of claim 25 wherein said weight ratio is provided by about 10 μg of pertussis toxoid, about 5 μg of filamentous haemagglutinin and about 5 μg of fimbrial agglutinogens in a single human dose.

27. The immunogenic composition of claim 24 comprising pertussis toxoid, filamentous haemagglutinin, the 69 kDa outer membrane protein and filamentous agglutinogens of *B. pertussis* in a weight ratio of about 10:5:5:3.

28. The immunogenic composition of claim 27 wherein said weight ratio is provided by about 10 μg of pertussis toxoid, about 5 μg of filamentous haemagglutinin, about

5 μg of the 69 kDa protein and about 3 μg of fimbrial agglutinogens in a single human dose.

29. The immunogenic composition of claim 24 comprising pertussis toxoid, filamentous haemagglutinin, the 69 kDa protein and fimbrial agglutinogens of *B. pertussis* in a weight ratio of about 20:20:5:3.

30. The immunogenic composition of claim 29 wherein said weight ratio is provided by about 20 μg of pertussis toxoid, about 20 μg of filamentous haemagglutinin, about 5 μg of the 69 kDa protein and about 3 μg of fimbrial agglutinogens in a single human dose.

31. The immunogenic composition of claim 24 further comprising at least one non-*Bordetella* immunogen.

32. The immunogenic composition of claim 31 wherein the non-*Bordetella* immunogen is selected from the group consisting of diphtheria toxoid, tetanus toxoid, capsular polysaccharide of *Haemophilus*, outer membrane protein of *Haemophilus*, hepatitis B surface antigen, polio, mumps, measles and rubella.

33. The immunogenic composition of claim 29 further comprising diphtheria toxoid in the amount of about 15 Lfs and tetanus toxoid in the amount of about 5 Lfs in a single human dose.

34. The immunogenic composition of claim 23 further comprising an adjuvant.

35. The immunogenic composition of claim 34 wherein the adjuvant is selected from the group consisting of aluminum phosphate, aluminum hydroxide, Quil A, QS21, calcium phosphate, calcium hydroxide, zinc hydroxide, a glycolipid analog, an octodecyl ester of an amino acid and a lipoprotein.

36. A method of immunizing a host against disease caused by *Bordetella*, comprising administering to the host an immunoeffective amount of the immunogenic composition of claim 21.

37. The method of claim 36 wherein the host is a human.